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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,785

10/17/2005

Kelly J Tucker

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EXAMINER

LARYEA, LAWRENCE N

ART UNIT

PAPER NUMBER

3768

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,785	<b>Applicant(s)</b> TUCKER, KELLY J	
	<b>Examiner</b> LAWRENCE N. LARYEA	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/19/2005</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8,19-22 are rejected under 35 U.S.C. **102(e)** as being anticipated by **Cribier et al (US Patent 4,777,951)**.

3. Re 1-8,19-22: **Cribier et al** teach a balloon catheter comprising: a flexible elongate body having a proximal portion and a distal portion, wherein the distal portion includes a curved portion terminating in a hooked portion at the extreme distal end, wherein curvature of the hooked portion is greater than curvature of the curved portion; at least three lumens (**12,14,16**) running lengthwise throughout the body, each having a port of entry at a proximal end thereof; an inflatable balloon (**22**) located on the exterior of the body with a distal end of the balloon terminating about 2 to 4 centimeters proximally of the curved portion of the distal portion of the body; and a port of exit

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located at a distal end of at least one of the lumens (**See Col.10, lines 54-67,Col.11, lines 4-31**).

4. Claims 23-25 are rejected under 35 U.S.C. **102(b)** as being anticipated by **Corday et al (US Patent 4,689,041)**.

5. Re Claims 23-25: **Corday et al** teaches a method inserting a catheter into a vein of the heart, occluding the blood flow in the vein; injecting a radiographic medium into the vein, wherein the occlusion of the blood flow causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the veins containing radiographic medium to obtain a map of the vein and the surrounding connected venous structure, including branches of the vein (**See Claim 1 (a-c) claim 9**).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cribier et al** as applied Claim 1,view of **Fuimaono et al (US Patent 6,866,662)** and further view of **Stewart et al (US Pub. 2005/0010095)**.

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8. **Cribier et al** teach a balloon catheter comprising the claimed invention see rejection supra **Cribier et al** does not teach that the balloon catheter comprises leads which runs through a lumen and the leads are connected to electrodes located on the curved portion of the body distally from the distal end of the balloon.

9. **Fuimaono et al** teach a balloon catheter comprises leads which runs through a lumen and the leads **(98)** are connected to electrodes **(96)** located on the curved portion of the body distally from the distal end of the balloon **(See Fig 15)**.

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the catheter system of **Cribier et al** to include leads which runs through a lumen and the leads **(98)** are connected to electrodes **(96)** located on the curved portion of the body distally from the distal end of the balloon **(See Fig 15)** of **Fuimaono et al** in order to monitor electrical activities during cardiac procedures **(See Col.19, lines 5-17)** as taught by **Fuimaono et al**.

10. **Stewart et al** teach a multi-purpose catheter which is used for both stenosis and arrhythmias treatment during cardiac treatment. **(See Paragraphs [0018],[0019]-[0023] and [0057])**.

Since **Cribier et al** teach that there is risk with major cardiac surgical procedure **(See Col.1, lines 22-25)**, it would have been obvious to one having ordinary skill in the art at the time invention was made to modify the catheter system of **Cribier et al** to include leads which runs through a lumen and the leads **(98)** are connected to electrodes located on the curved portion of the body distally from the distal end of the balloon of **Fuimaono et al** in order to monitor electrical activities during cardiac

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procedures (**See Col.19, lines 5-17 of Fuimaono et al** ) as taught by **Fuimaono et al**, and also to modify the catheter system of **Cribier et al** wherein a multi-purpose catheter can be used to provide different diagnostic and therapeutic functions during a cardiac treatments as taught by **Stewart et al**.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Corday et al (US Patent 4,689,041)** as applied Claim 23, in view of **De la Rama et al (US Patent 5,951,471)**.

12. **Corday et al (US Patent 4,689,041)** teach the claimed invention see rejection supra, wherein the catheter can be use for cardiac treatment or diagnosis (**Col.4, lines 11-24 and Col.3, lines 13-17**), **Corday et al** does not teach measuring the electrical conduction pattern of the venous structure and mapping the electrical conduction pattern.

13. **De la Rama et al (US Patent 5,951,471)** teach a catheter can be use for cardiac treatment or diagnosis method comprising determining a location having an aberrant electrical conduction pattern in the heart of the subject from the map of the electrical conduction pattern (**See Abstract and Claims 1-5**) to assist in a catheter-based ablation of atrial flutter indications (**Col.5, lines 4-40**).

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the catheter method of **Corday et al** during cardiac treatment or diagnosis **to** determine a location having an aberrant electrical conduction

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pattern in the heart of the subject from the map of the electrical conduction pattern of to assist in a catheter-based ablation of atrial flutter indications (**See Col.5, lines 4-40, Col.1, lines 7-10**) as taught by **De la Rama et al.**

14. Claims 27-30,are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cribier et al (US Patent 4,777,951)** as applied in claim 1, in view of **Corday et al (US Patent 4,689,041)**.

15. **Cribier et al** teach the claimed invention see rejection supra, including inserting a guidewire into one of the lumens of the balloon catheter to form a guidewire-containing balloon catheter (**See Col.12, lines 35-39**).

16. **Cribier et al** does not teach injecting a radiographic dye into the vein through a lumen of the guidewire-containing balloon catheter, wherein the occlusion of the blood flow by the balloon causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the vein and connected venous structure containing the radiographic dye so as to obtain a map of the vein and the surrounding connected venous structure, including branches of the vein.

17. **Corday et al (US Patent 4,689,041)** teaches a method inserting a catheter into a vein of the heart, occluding the blood flow in the vein ; injecting a radiographic medium into the vein, wherein the occlusion of the blood flow causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the veins containing radiographic medium to obtain a map (Angiography) of the vein and the surrounding connected venous

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structure (Angiography), including branches (Angiography ) of the vein (**See Claim 1 (a-c) claim 9**).

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the method of **Cribier et al** injecting a radiographic dye into the vein through a lumen of the guidewire-containing balloon catheter, wherein the occlusion of the blood flow by the balloon causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the vein and connected venous structure containing the radiographic dye so as to obtain a map of the vein and the surrounding connected venous structure, including branches of the vein of **Corday et al** in order to visualize various vessel of the cardiac system (angiography) during cardiac treatment or diagnosis as taught by **Corday et al**.

18. Claims 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cribier et al**, as applied in claims 1 and 10 in view of **Corday et al**, **De la Rama et al** and further view of **Rosenman et al (US 2003/0229386)**.

19. Re Claims 31-45: **Cribier et al** teach the claimed invention see rejection supra, including inserting a guidewire into one of the lumens of the balloon catheter to form a guidewire-containing balloon catheter (**See Col.12, lines 35-39**). **Cribier et al** does not teach injecting a radiographic dye into the vein through a lumen of the guidewire-containing balloon catheter, wherein the occlusion of the blood flow by the balloon causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the vein and



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connected venous structure containing the radiographic dye so as to obtain a map of the vein and the surrounding connected venous structure, including branches of the vein, measuring the electrical conduction pattern of the venous structure and mapping the electrical conduction pattern and implanting a pacemaker lead in the heart.

20. **Corday et al** teach a method inserting a catheter into a vein of the heart, occluding the blood flow in the vein ; injecting a radiographic medium into the vein, wherein the occlusion of the blood flow causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the veins containing radiographic medium to obtain a map (Angiography) of the vein and the surrounding connected venous structure (Angiography), including branches (Angiography ) of the vein (**See Claim 1 (a-c) claim 9**).

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the method of **Cribier et al** injecting a radiographic dye into the vein through a lumen of the guidewire-containing balloon catheter, wherein the occlusion of the blood flow by the balloon causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and imaging the vein and connected venous structure containing the radiographic dye so as to obtain a map of the vein and the surrounding connected venous structure, including branches of the vein of **Corday et al** in order to visualize various vessel of the cardiac system (angiography) during cardiac treatment or diagnosis as taught by **Corday et al**.

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21. **Cribier et al** and **Corday et al** teach the claimed invention see rejection supra, **Cribier et al** and **Corday et al** do not teach measuring the electrical conduction pattern of the venous structure and mapping the electrical conduction pattern and implanting a pacemaker lead in the heart and implanting a pacemaker lead in the heart.

22. **De la Rama et al (US Patent 5,951,471)** teach catheter method comprising determining a location having an aberrant electrical conduction pattern in the heart of the subject from the map of the electrical conduction pattern (**See Abstract and Claims 1-5**) to assist in a catheter-based ablation of atrial flutter indications (**Col.5, lines 4-40**).

It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the catheter method of **Cribier et al** and **Corday et al** comprising determining a location having an aberrant electrical conduction pattern in the heart of the subject from the map of the electrical conduction pattern of to assist in a catheter-based ablation of atrial flutter indications (**See Col.5, lines 4-40**) as taught by **De la Rama et al**.

23. The combination of **Cribier et al** and **Corday et al** as modified **De la Rama et al** do not teach that the catheter method comprising implanting a pacemaker lead and implanting a pacemaker lead in the heart.

24. **Rosenman et al** teach a catheter method comprising a **catheter method** suitable for implanting a pacemaker lead in the heart (**See Paragraph [0006]-[0018]**) in order to help a doctor to detect abnormal heart rhythms and apply electrical shocks to the heart to keep the heart at a desired pace (**See Paragraph [0002]**).

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It would have been obvious to one having ordinary skill in the art at the time invention was made to modify the catheter method of **Cribier et al** and **Corday et al** as modified **De la Rama et al** comprising a catheter method suitable for implanting a pacemaker lead in the heart of **Rosenman et al** in order to help a doctor to detect abnormal heart rhythms and apply electrical shocks to the heart to keep the heart at a desired pace as taught by **Rosenman et al**.

### ***Conclusion***

**25. Makower (Patent 6,283,983)** teaches a method inserting a catheter into a vein of the heart, occluding the blood flow in the vein; injecting a radiographic medium into the vein, wherein the occlusion of the blood flow causes retrograde flow of the blood and the dye into the surrounding connected venous structure of the vein, including branches of the vein; and d) imaging the veins containing radiographic medium to obtain a map (venous tree) of the vein and the surrounding connected venous structure, including branches of the vein (**See Col.8, lines 26-34**).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAWRENCE N. LARYEA whose telephone number is (571)272-9060. The examiner can normally be reached on 9:30 a.m.-5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LNL

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

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